



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN, JR. ARNOLD SCHWARZENEGGER, GOVERNOR

WHOLESALE DANGEROUS DRUGS & DANGEROUS DEVICES SELF- ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 18.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (**B & P B&PC**) section 4022.
(http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address (optional) _____

Ownership: Please mark one

☐ sole owner ☐ partnership ☐ corporation ☐ LLC

☐ non- licensed owner ☐ Other (please specify) _____

CA Wholesaler Permit # _____ Expiration Date _____

Other Permit # _____ Expiration Date _____

DEA Registration # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Daily _____ Sat _____ Sun _____ 24 Hours ☐

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License # _____ Expiration Date _____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _____ DR#/RPH# _____ Exp. Date _____
2. _____ DR#/RPH# _____ Exp. Date _____
3. _____ DR#/RPH# _____ Exp. Date _____
4. _____ DR#/RPH# _____ Exp. Date _____
5. _____ DR#/RPH# _____ Exp. Date _____
6. _____ DR#/RPH# _____ Exp. Date _____
7. _____ DR#/RPH# _____ Exp. Date _____
8. _____ DR#/RPH# _____ Exp. Date _____
9. _____ DR#/RPH# _____ Exp. Date _____
10. _____ DR#/RPH# _____ Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐

Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (~~B & P~~ B&PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐

Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note:: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (~~B & P~~ B&PC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

2. Facility

Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐

Are clean and orderly

☐ ☐ ☐

Are well ventilated

☐ ☐ ☐

Are free from rodents and insects

☐ ☐ ☐

Are adequately lit

☐ ☐ ☐

Have plumbing in good repair

☐ ☐ ☐

Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

☐ ☐ ☐

Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☐ ☐ ☐

Are dangerous drugs and dangerous devices stored in a secured and locked area?
(CCR 1780[a])

☐ ☐ ☐

Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

Yes No N/A

☐ ☐ ☐

Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

☐ ☐ ☐

The wholesale premises is equipped with the following specific security features:

☐ ☐ ☐

There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐

The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐

The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

Yes No N/A

☐ ☐ ☐

Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs?
(~~B & P~~ B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

☐ ☐ ☐

The facility is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN

Yes No N/A

☐ ☐ ☐

The facility receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

☐ ☐ ☐

The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B & P B&PC 4081[b])

☐ ☐ ☐

Is the designated representative-in-charge responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B & P B&PC 4160[d])

☐ ☐ ☐

The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B & P B&PC 4305.5[a])

☐ ☐ ☐

The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B & P B&PC 4160[d], 4331[c]) The

appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.

Yes No N/A

☐ ☐ ☐

The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (~~B & P~~ B&PC 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

4. Designated Representative/Pharmacist

Yes No N/A

☐ ☐ ☐

If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (~~B & P~~ B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐

Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (~~B & P~~ B&PC 4163[b], 4169)

Yes No N/A

☐ ☐ ☐

If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (~~B & P~~ B&PC 4081, 4332)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐

When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐

When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐

Is all drug stock open for inspection during regular business hours? (~~B & P~~
B&PC 4081[a])

☐ ☐ ☐

Are all drugs you order maintained in a secure manner at your licensed wholesale premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (~~B & P~~ B&PC 4167)

☐ ☐ ☐

Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (~~B & P~~ B&PC 4342[a])

~~Yes No N/A~~

☐ ☐ ☐

Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐

Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐

Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

- ☐ ☐ ☐ When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

- ☐ ☐ ☐ Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

Describe how you verify a business or person is appropriately licensed. (~~B & P~~ B&PC 4059.5[a] [b][d], ~~B & P~~ B&PC 4169)

List any businesses or individuals that order drugs from you that are not licensed according to the list above:

Yes No N/A

- ☐ ☐ ☐ Are drugs only furnished by your business to an authorized person? (~~B & P~~ B&PC 4163[a]) Note: An authorized person can be a business or natural person.

- ☐ ☐ ☐ Does your business only receive drugs from a pharmacy if:
- ☐ ☐ ☐ the pharmacy originally purchased the drugs from you?
- ☐ ☐ ☐ your business is a "reverse distributor"?
- ☐ ☐ ☐ the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (~~B & P~~ B&PC 4126.5[a])

Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

- ☐ ☐ ☐ transacted with a business licensed with this board as a wholesaler or pharmacy?
- ☐ ☐ ☐ free of adulteration as defined by the CA Health & Safety Code section 111250?
- ☐ ☐ ☐ free of misbranding as defined by CA Health & Safety Code section 111335?
- ☐ ☐ ☐ **confirmed** to not be beyond their use date (expired drugs)? (~~B & P~~ B&PC 4169)

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

- If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:
- | Yes | No | N/A | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | comply with all CA pharmacy laws related to the distribution of drugs? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | comply with the pharmacy law of the receiving state within the United States? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | comply with the statutes and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | comply with all laws of the receiving foreign country related to the wholesale distribution of drugs? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | comply with all applicable federal regulations regarding the exportation of dangerous drugs? |

Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (~~B & P~~ B&PC 4059.5[e])

- | Yes | No | N/A | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). Effective January 1, 2009, Commencing on July 1, 2017, an electronic pedigree must accompany all drugs (B & P <u>B&PC</u> 4163), even those for which your business is an authorized distributor. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B & P <u>B&PC</u> 4380) |

☐ ☐ ☐ Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (~~B & P~~ B&PC 4341, ~~B & P~~ B&PC 651, CCR 1766)

☐ ☐ ☐ Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (~~B & P~~ B&PC 650)

Yes No N/A

☐ ☐ ☐ Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (~~B & P~~ B&PC 4066, CFR 1301.25)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

~~Yes~~ ~~No~~ ~~N/A~~

☐ ☐ ☐ Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (~~B & P~~ B&PC 4166[a])

List the common carriers (shipping or delivery companies) you use.

CORRECTIVE ACTION OR ACTION PLAN

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

- ☐ ☐ ☐ Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (~~B & P~~ B&PC 4059.5[a])
- ☐ ☐ ☐ Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (~~B & P~~ B&PC 4059[d])
- ☐ ☐ ☐ All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (~~B & P~~ B&PC 4059.5[c])
- ☐ ☐ ☐ If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (~~B & P~~ B&PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN

11. Controlled Substances

Yes No N/A

- ☐ ☐ ☐ Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

~~Yes No N/A~~

- ☐ ☐ ☐ Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

- ☐ ☐ ☐ Are DEA requirements for storage of Schedule III controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

- ☐ ☐ ☐ Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])
- ☐ ☐ ☐ Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])
- ☐ ☐ ☐ Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, has created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

List the individuals at this location authorized by power of attorney to order controlled substances.

Yes No N/A

- ☐ ☐ ☐ Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)
- ☐ ☐ ☐ If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)
- ☐ ☐ ☐ Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])
- ☐ ☐ ☐ If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])
- ☐ ☐ ☐ If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

Yes No N/A

☐ ☐ ☐ If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

☐ ☐ ☐ When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 form? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed ~~DEA~~ DEA 222 order form sent to DEA by the close of that month? (CFR 1309.13[b])

☐ ☐ ☐ For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances?

☐ ☐ ☐ Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (~~B & P~~ B&PC 4081, CCR 1718, CFR 1305.09[d], 1305.17[a] [b], and H & S 11252, 11253, 1304.03)

Yes No N/A

☐ ☐ ☐ Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

- ☐ ☐ ☐ Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
- ☐ ☐ ☐ Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)
- ☐ ☐ ☐ Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])
- ☐ ☐ ☐ Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

12. Policies and Procedures

Does this business maintain and adhere to policies and procedures for:

Yes No N/A

- | | | | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Receipt of drugs? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Security of drugs? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Storage of drugs? (including maintaining records to document proper storage) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Inventory of drugs? (including correcting inaccuracies in inventories) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Distributing drugs? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Identifying, recording and reporting theft or losses? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Correcting errors? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Physically quarantining and separating: |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | returned, damaged, outdated, deteriorated, misbranded or adulterated drugs? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | drugs that have been partially used? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | drugs where the outer or secondary seals on the container have been broken? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f]) |

CORRECTIVE ACTION OR ACTION PLAN _____

13. Training

Yes No N/A

☐ ☐ ☐

Is training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

CORRECTIVE ACTION OR ACTION PLAN

14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐

Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (~~B & P~~ B&PC 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐

Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (~~B & P~~ B&PC 4059[d])

☐ ☐ ☐

Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])

☐ ☐ ☐

Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐

Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN

15. Record Keeping Requirements

Yes No N/A

- ☐ ☐ ☐ Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (~~B & P~~ B&PC 4059[b])
- ☐ ☐ ☐ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (~~B & P~~ B&PC 4081[a], 4105[c], 4081, 4332, 4059.5[a]) Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.
- ☐ ☐ ☐ Are all purchase and sales records retained in a readily retrievable form? (~~B & P~~ B&PC 4105[a])
- ☐ ☐ ☐ Is a current accurate inventory maintained for all dangerous drugs? (~~B & P~~ B&PC 4081, 4332, 1718)
- ☐ ☐ ☐ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (~~B & P~~ B&PC 4105[b])
- ☐ ☐ ☐ Are required records stored off-site only if a board issued written waiver has been granted?

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address _____

Yes No N/A

- ☐ ☐ ☐ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])
- ☐ ☐ ☐ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

Yes No N/A

- ☐ ☐ ☐ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

- ☐ ☐ ☐ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

- ☐ ☐ ☐ Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (~~B & P~~ B&PC 4162[a][4]):
-
-

Yes No N/A

- ☐ ☐ ☐ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (~~B & P~~ B&PC 4083)
- ☐ ☐ ☐ Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (~~B & P~~ B&PC 4315[e])
- ☐ ☐ ☐ If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

- ☐ ☐ ☐ A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (~~B & P~~ B&PC 4101[b], 4305.5[c]).
- ☐ ☐ ☐ The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (~~B & P~~ B&PC 4305.5[a])

~~Yes No N/A~~

- ☐ ☐ ☐ The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

- ☐ ☐ ☐ The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

- ☐ ☐ ☐ Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
- ☐ ☐ ☐ The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (~~B & P~~ B&PC 4201[i], CCR 1709[b])
- ☐ ☐ ☐ When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (~~B & P~~ B&PC 4164[a])
- ☐ ☐ ☐ Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:
1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
 2. identify purchases of any dangerous drugs at preferential or contract prices
 3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (~~B & P~~ B&PC 4164[b])
- ☐ ☐ ☐ I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (~~B & P~~ B&PC 4201[g])
- ☐ ☐ ☐ The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)
- ☐ ☐ ☐ If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

[space inserted]

CORRECTIVE ACTION OR ACTION PLAN _____

17. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (~~B & P~~ B&PC 4059.5[e], 4107, CFR 1305.11[a], ~~B & P 4059.5[e]~~)

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____
hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

Legal References

All references to California Business & Professions Code (~~B & P~~ B&PC) are Chapter 9, Division 2 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Code of Regulations (CCR) are to Title 16 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Health & Safety Code (H & S) are to Division 10, Uniform Controlled Substances Act (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) or Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws <http://www.dhs.ca.gov/fdb/PDF/Sherman%202006.PDF>

All references to United States Code of Federal Regulations (CFR) are Title 21, Chapter II Part Part 1300, Drug Enforcement Administration, Food and Drugs and codified Controlled Substances Act (CSA) (<http://www.deadiversion.usdoj.gov/21cfr/index.html>).

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: ~~fax:~~ (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:

Law-Tech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program
Phone: (800) 522-9198 (24 hours a day)

Prescriber Boards:

Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815
Phone: (800) 633-2322
Phone: (916) 263-2382
Fax: ~~fax:~~ (916) 263-2944
<http://www.mbc.ca.gov>

Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815
Phone: (916) 263-2300
Fax: ~~fax:~~ (916) 263-2140
<http://www.dbc.ca.gov>

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-7697
Fax: ~~fax:~~ (916) 574-8637
<http://www.rn.ca.gov/>

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: ~~fax:~~ (916) 575-7292
<http://www.optometry.ca.gov/>

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento, CA 95834
Phone: (916) 928-8390
Fax: ~~fax:~~ (916) 928-8392
<http://www.ombc.ca.gov>

Physician Assistant Committee
2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
fax: (916) 263-2671
<http://www.pac.ca.gov>

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: ~~fax:~~ (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board
2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: ~~fax:~~ (916) 263-2621
<http://www.vmb.ca.gov>

Federal Agencies:

Food and Drug Administration

– Industry Compliance

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The Drug Enforcement Administration may be contacted at:

DEA Website:

<http://www.dea diversion.usdoj.gov>

Online Registration – New Applicants:

http://www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.dea diversion.usdoj.gov/drugreg/change_requests/index.html

Online DEA 106 Theft/Loss Reporting:

<http://www.dea diversion.usdoj.gov/webforms/app106Login.jsp>

Controlled Substance Ordering System

(CSOS): <http://www.deaecom.gov/>

DEA Registration Support (all of CA):

(800) 882-9539

DEA - Los Angeles

255 East Temple Street, 20th Floor

Los Angeles, CA 90012

Registration: (888) 415-9822 or (213) 621-6960

~~(Registration)~~

Diversion or Investigation: (213) 621-6942

~~(Diversion or Investigation)~~

DEA – San Francisco

450 Golden Gate Avenue, 14th Floor

San Francisco, CA 94102

Registration: (888) 304-3251

Theft Reports or Diversion: (415) 436-7900

DEA - Sacramento

4328 Watt Avenue

Sacramento, CA 95821

Registration: (888) 304-3251 or (415) 436-7900

~~(415) 436-7900~~

Diversion or Investigation: (916) 480-7250

DEA - Riverside

4470 Olivewood Avenue

Riverside, CA 92501-6210

Registration: (888) 415-9822 or (213) 621-6960

~~(213) 621-6960~~

Diversion or Investigation: (951) 328-6200

DEA - Fresno

2444 Main Street, Suite 240

Fresno, CA 93721

Registration: (888) 304-3251 or (415) 436-7900

~~(415) 436-7900~~

Diversion or Investigation: (559) 487-5406

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue

San Diego, CA 92123-1637

Registration: (800) 284-1152

Diversion or Investigation: (858) 616-4100

DEA – Oakland

1301 Clay Street, Suite 460N

Oakland, CA 94612

Registration: (888) 304-3251

Diversion or Investigation: (510) 637-5600

DEA – San Jose

One North First Street, Suite 405

San Jose, CA 95113

Registration: (888) 304-3251

Diversion or Investigation: (408) 291-2631

DEA – Redding

310 Hensted Drive, Suite 310

Redding, CA 96002

Registration: (888) 304-3251 or (415) 436-7900

~~(415) 436-7900~~

Diversion or Investigation: (530) 246-5043